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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,298	08/22/2003	Stefan A. Sharpe	PD06063	9222

24265 7590 06/29/2006

SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER

ALSTRUM ACEVEDO, JAMES HENRY

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/646,298		SHARPE ET AL.	
	Examiner		Art Unit	
	James H. Alstrum-Acevedo		1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1-20 are pending. Receipt and consideration of Applicants IDS, amended claims, and arguments/remarks filed on April 25, 2006 is acknowledged.

Information Disclosure Statement

It was noted that the PG-PUB number cited on the IDS submitted on April 25, 2006, corresponding to application 11/071,078 is incorrectly listed, as 04-0086465, and should be 20050147565.

Specification

The objections to the disclosure because of an apparent typographical error in the chemical formula for the propellant HFA 227 on page 3, line 6, also known as HFC 227 or 1,1,1,2,3,3,3 heptafluoropropane and the improper use of the trademarks as described on page 2 of the previous office action **are withdrawn**, per Applicant's amendments.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

The rejection of claims 1-20 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is maintained**. It is noted that Applicant has amended claim 1 to

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remove the indefinite term "substantially" and has amended claims 8, 9, 19, and 20 to correct the lack of antecedent basis for the term "the fine particles."

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 1-7 under 35 U.S.C. 103(a) as being unpatentable over Fassberg et al. (U.S. Patent No. 5,474,759) **is maintained** for the reasons of record on pages 5-7 of the previous office action.

The rejection of claims 1-6, 8-17, and 19-20 under 35 U.S.C. 103(a) as being unpatentable over Dickinson et al. (WO 99/51205) in view of Kaplan et al. (U.S. Patent Application 2002/0076382 A1) **is maintained**, for the reasons of record on pages 7-11 of the previous office action.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection of claims 1-5, 7, and 13-18 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 5,474,759 **is maintained**, for the reasons of record on pages 11-12 of the previous office action.

The rejection of claims 1, 2-5, and 13-17 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 10, and 12 of copending Application No. 10/967,719 (copending '719) in view of Kaplan et al. (U.S. Patent Application US2002/0076382) **is maintained** for the reasons of record on pages 12-14 of the previous office action.

The rejection of claims 1, 10, and 13 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 5-7 of copending Application No. 10/649,398 (copending '398) **is maintained** for the reasons of record on pages 14-16 of the previous office action.

Claims 1-20 (all claims) are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 and 20-26 of copending Application No. 11/071,078 (copending '078) (cited in Applicant's IDS, submitted on April 25, 2006) in view of García-Marcos et al. ("Inhaled Corticosteroids Plus Long-Acting Beta₂-agonists as a Combined Therapy in Asthma," *Expert Opin. Pharmacother.* 2003, 4(1), pp 23-39). Both the claims of the instant application and copending '078 claim suspension formulations comprising HFA 227 (1,1,1,2,3,3,3-heptafluoropropane) and

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mometasone furoate as the active agent, as well as metered dose inhalers containing said formulation, and processes of making said suspension aerosol formulations. The difference between the instant application and copending '078 is that copending '078 recites compositions also comprising formoterol fumarate. This deficiency is cured by the teachings of García-Marcos. García-Marcos teaches that the combination of an anti-inflammatory steroid (e.g. mometasone furoate or budesonide) with a long-acting bronchodilator, such as formoterol furoate is known (see pages 26-28). Furoate is a known ester derivative of formoterol. Because the combination of an anti-inflammatory steroid with a bronchodilator is known, the cited claims of the instant application are *prima facie* obvious over the cited claims of copending '078.

This is a provisional obviousness-type double patenting rejection.

Response to Arguments

Applicant's arguments filed, April 25, 2006, have been fully considered but they are not persuasive. Applicants' arguments rely on the assertion that HFA 227 is only a propellant and cannot be construed to be a carrier. Applicant defines a carrier on page 6, line 24 through page 7, line 1 to mean, "...an inert substance in which or on which the active drug ingredient(s) and excipient(s) if present are dispersed. Applicant's disclosure is clearly drawn to dispersion systems (see for example, page 9, lines 22-24 and page 10, lines 12-13). Suspensions are also dispersions. Nowhere in the instant application is there support that the claimed formulations and methods utilize a system wherein the active agent(s) and/or excipient(s) are dissolved. Therefore, in light of the Applicant's disclosure, **HFA 227 is both a carrier and a propellant**, and the term "free of a carrier" is deemed repugnant to the art. As such, Applicants' arguments

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regarding the prior art rejections under §103(a) and on the grounds of obviousness-type double patenting are unpersuasive.

Conclusion

Claims 1-20 are rejected. No claims are allowed.

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on April 25, 2006 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571)

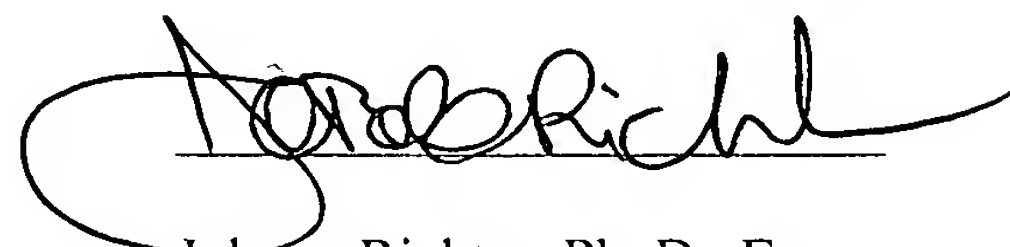
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272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0664. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James H. Alstrum-Acevedo, Ph.D.
Patent Examiner
Technology Center 1600

A handwritten signature in black ink, appearing to read "Johann Richter", written over a horizontal line.

Johann Richter, Ph. D., Esq.
Supervisory Patent Examiner
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